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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/817,704	08/25/1997	ANTHONIUS J. SWAAK	P8214-7002	8580

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03/17/2005

ARENT FOX KINTER PLOTKIN & KAHN, PLLC
1050 CONNECTICUT AVENUE, N.W.
SUITE 600
WASHINGTON, DC 20036-5339

EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/817,704

Applicant(s)

SWAAK, ANTHONIUS J.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/29/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,20,23-26 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,20,23-26 and 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1644

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 2/09/05 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment and remarks, filed 2/09/05, have been entered.
2. Claims 18, 20, 23-26, 31-36 are currently pending in this application.
3. Applicant's amendment and remarks filed 2/09/05 are acknowledged. In view of Applicant's amendment, specifically the inclusion of method steps requiring the identifying of patients suffering from the recited conditions, as well as the identifying of said patients benefiting from Epo treatment, the previous rejections under 35 U.S.C. 102 and 103(a) have been withdrawn. Additionally, given the instant amendment, the previous rejection under 35 U.S.C. 112, first paragraph for the recitation of a method "wherein the patient has not been treated with iron" has also been withdrawn.
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 18, 20, 23-26, and 31-36, stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed, for the reasons of record as set forth in the paper mailed 12/04/03. This is a new matter rejection.

Art Unit: 1644

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) "A method of treating morning stiffness, loss of grip strength, painful joints, or swollen joints" (Claim 18).

B) "A method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level" (Claim 20).

Applicant's arguments, filed 2/09/05, have been fully considered but they are not persuasive. Applicant argues that the recitation in original Claim 5 of the use of Epo in the preparation of a pharmaceutical for the treatment of symptoms associated with rheumatoid arthritis (RA) supports the claims.

As set forth previously, original "use" claims drawn to the preparation of a pharmaceutical are insufficient support for the instant claims drawn to a method of treatment. And note that "painful joints" is recited nowhere in the specification, thus, this limitation finds support only in the method of preparing a pharmaceutical recited in the original "use" claims. Additionally, the original claims were drawn only to morning stiffness, painful and swollen joints, loss of grip strength, and pain, associated with the symptoms of RA and not the morning stiffness, painful and swollen joints, loss of grip strength, and pain, from any source (in all but Claims 32 and 33) as is now claimed. It is noted that Applicant has not addressed the rejection of part B).

6. The following are new grounds for rejection necessitated by Applicant's amendment.

7. Claims 18, 20, 23-26, and 31-36, are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) a method of treating consisting of identifying a patient, administering Epo to said patient, and identifying that said patient that suffers from morning stiffness, loss of grip

Art Unit: 1644

strength, painful joints, or swollen joints has a lower level of morning stiffness, loss of grip strength, painful joints, or swollen joints after treatment.


B) a method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level consisting of identifying a patient, administering Epo to said patient, and identifying that said patient has an ameliorated erythrocyte sedimentation rate or C-reactive protein level.

Applicant indicates that no new matter has been added but cites no support for the instant amendments.

A review of the specification discloses that the new limitations are found only in a specific example in the context of treating ACD patients (i.e., a specific subset of RA patients) with a specific dosage of Epo, for a specific timeframe, and not in the broad context of the instant claims.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

9. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.


3/9/08

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600